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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/754,204 | 01/05/2001 | Daniel Gelber | XMP 2031 | 3336 |

30868 7590 11/25/2003

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ARLINGTON, VA 22202

EXAMINER

WITZ, JEAN C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1651

DATE MAILED: 11/25/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/754,204

Applicant(s)

GELBER ET AL.

Examiner

Jean C. Witz

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-126 is/are pending in the application.
- 4a) Of the above claim(s) 8, 10-52, 62-64, 70-72, 74-114 and 124-126 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9, 53-61, 65-69, 73 and 115-123 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species 1: an immune booster

Subspecies 1: zinc or salts thereof

Subspecies 2: herbs of the genus Echinacea

Subspecies 3: herbs of the genus Sambucus

Subspecies 4: herbs of the genus Goldenseal

Species 2: an antioxidant

Subspecies 1: a bioflavonoid or an herbal extract containing a
bioflavonoid

Subspecies 2: ascorbic acid or salts thereof

Subspecies 3: garlic or extracts thereof

Subspecies 4: green tea or extracts thereof

Subspecies 5: herbs of the genus Astragalus

Species 3: a liver protectant

Species 4: joint relief agents

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species and within that species, if listed, a single subspecies for prosecution on the merits to which

the claims shall be restricted if no generic claim is finally held to be allowable.

Currently, claims 1-5 and 65-69 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Arlir Amato on February 24, 2003 a provisional election was made with traverse to prosecute the invention of the species of joint relief agents, claims 9, 53-61, 73 and 115-123. Affirmation of this election must be made by applicant in replying to this Office action. Claims ~~6~~8, 10-52, 62-64, 70-72, 74-

114 and 124-126 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

Claims 3 and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Markush group that recites "the group consisting of acetaminophen, non-steroidal anti-inflammatory drugs (NSAID's), and mixtures thereof" is improper because the members of the group are not mutually exclusive. Acetaminophen is considered to fall within the category of NSAIDs.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 9, 53-55, 60, 65-69, 73, 115-117 and 122 are rejected under 35 U.S.C. 102(b) as being anticipated by FR 4804, DE 2103387 and U.S. Patent 3,008,874.

The references disclose a composition containing various NSAIDs (indomethacin and aspirin) and glucosamine, where the glucosamine potentiates the activity of the NSAID. Therefore, the claims are anticipated by the disclosure of the prior art reference.

Claims 1-5, 9, 53-55, 61, 65-69, 73, 115-117 and 123 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 09087174 and JP 04018022.

The references disclose a composition containing various NSAIDs (piroxicam or ibuprofen) and chondroitin. Therefore, the claims are anticipated by the disclosure of the prior art reference.

Claims 1-5, 9, 53-56, 58, 60-61, 65-69, 73, 115-118, 120 and 122-123 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by U.S. Patent 6,608,041.

The reference discloses a composition containing acetaminophen and chondroitin or glucosamine. Therefore, the claims are anticipated by the disclosure of the prior art reference.

Claims 1-5, 9, 53-55, 60-61, 65-69, 73, 115-117, and 122-123 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by U.S. Patent 6,399,093.

The reference discloses a composition containing various NSAIDs (ibuprofen or diclophenac) and chondroitin or glucosamine. Therefore, the claims are anticipated by the disclosure of the prior art reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 57, 59, 119 and 121 are rejected under 35 U.S.C. 103(a) as being unpatentable over FR 4804, U.S. Patent 3,008,874 and U.S. Patent 6,608,041 in view of Muriel et al., Campos et al., and Kucharz et al.

The references disclose composition containing various NSAIDs (acetaminophen and aspirin) and either glucosamine or chondroitin.

Both Muriel et al. and Campos et al. teach that silymarin (milk thistle) can protect against acetaminophen hepatotoxicity. Kucharz et al. teach that silymarin is hepatoprotective against liver damage due to acetylsalicylic acid (aspirin) or naproxen. It would have been obvious to one of ordinary skill in the art at the time the invention was made to select a conventional NSAID to combine with a joint relief agent of either glucosamine or chondroitin because the prior art indicates that various combinations of conventional NSAIDs with glucosamine or chondroitin have been taught in the prior art. The inclusion of milk thistle is motivated by the potential for hepatotoxicity of acetaminophen thereby providing protection against said hepatotoxicity.

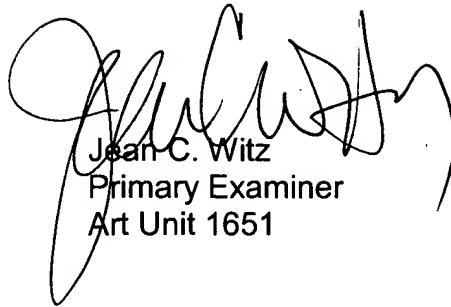
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-3073. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-Th and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Jean-C. Witz
Primary Examiner
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